UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

IN RE: ZANTAC (RANITIDINE) PRODUCTS LIABILITY LITIGATION

MDL NO. 2924
20-MD-2924

JUDGE ROBIN L. ROSENBERG
MAGISTRATE JUDGE BRUCE E. REINHART

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THIS DOCUMENT RELATES TO: ALL CASES ON EXHIBITS A AND B, 20-MD-2924

ORDER ENTERING FINAL JUDGMENT IN ALL MEDICAL MONITORING CLASS ACTION CASES AND DISMISSING ALL ECONOMIC LOSS CLASS ACTION CASES FOR LACK OF STANDING

In this MDL, the Plaintiffs filed two types of class action claims: medical monitoring class action claims and economic loss class action claims. To resolve these class action claims, the Court, through its case management plan, first addressed the issue of general causation—can ranitidine (the drug at issue in this MDL) cause cancer in humans? Were the Plaintiffs' personal injury claims to survive the general causation challenges, the Plaintiffs then could file their motion for class certification pursuant to the Court's case management plan. The Plaintiffs' claims, however, did not survive the *Daubert* challenges.

Before the Plaintiffs moved for class certification, the Court concluded that the Plaintiffs have no reliable evidence that ranitidine could cause certain cancers. In light of its *Daubert* ruling, the Court undertook to determine whether the Plaintiffs still could move for certification of their medical monitoring and economic loss class action claims. In this Order, the Court sets forth why the Plaintiffs cannot do so. As such, the Court enters final judgment in the medical monitoring class action cases and dismisses without prejudice all of the economic loss class action cases for lack of standing.

To explain how the Court reaches this conclusion, first the Court outlines the procedural history of the class action claims in this MDL, focusing on the Plaintiffs' contention that they had standing to bring their economic loss class action claims. Then the Court analyzes the impact of the Court's *Daubert* ruling on the medical monitoring and economic loss class action claims.

I. Background on the Plaintiffs' Standing Theory

Throughout the course of this MDL, the Plaintiffs had a standing theory. The Plaintiffs' standing theory was clearly pled; it was the centerpiece of all of the Plaintiffs' standing arguments; and, this standing theory survived multiple rounds of motions to dismiss. In this section, the Court reviews those allegations in the Plaintiffs' complaints relevant to standing, the Plaintiffs' arguments opposing the Defendants' motions to dismiss based on lack of standing, and the Court's rulings on standing.

In the Plaintiffs' class action complaint first filed in the MDL, the Plaintiffs alleged that ranitidine was "inherently defective, unreasonably dangerous, [] not fit to be used for [its] intended purpose," and, therefore, worthless. *See* DE 889 (referring to ranitidine as "dangerous" 1,656 times). The Plaintiffs did not allege in their complaint that ranitidine was otherwise ineffective or did not perform as advertised. The Defendants moved to dismiss the complaint in its entirety for lack of standing, arguing that the Plaintiffs failed to state an injury-in-fact fairly traceable to the Defendants. *See, e.g.*, DE 1630 at 26-27. In opposition, the Plaintiffs argued that they had suffered an economic injury-in-fact when they purchased ranitidine since it was a "worthless, dangerous drug" that created NDMA. DE 1980 at 10-11, 25; *see also* DE 2515 at 13 ("[The Plaintiffs] state that they suffered an economic injury, (*i.e.*, a 'pocketbook injury') by paying for misbranded

and/or adulterated ranitidine products that should not have been available for sale, and which were economically worthless."). They suffered an economic injury-in-fact

> not simply because something that is illegal to sell is automatically worthless merely because of that fact. It is because Congress made a particular kind of judgment in the Food, Drug and Cosmetics Act about what types of things are safe for people to consume, and it judged that a misbranded or adulterated drug or supplement would be unsafe, and for that reason illegal, not for a different reason, and that is what makes it an injury in fact.

Dec. 14, 2020, Hearing Tr. at 127-28. In this way, the Plaintiffs' standing theory rested on four points: ranitidine causes cancer, was unsafe, should not have been sold, and, therefore, was worthless, or at least worth less. *Id.* at 129-31.

In its Order on the first round of motions to dismiss, the Court determined that it could not "undertake a full Article III standing analysis" because the complaint under review was a shotgun pleading, but the Court did reach certain conclusions about standing. DE 2515 at 13-14. First, in line with the parties' agreement, standing for the class action claims should be evaluated before the class certification stage of the proceedings. *Id.* at 25. Second, the Court would evaluate standing on a claim-by-claim basis. *Id.* at 28. Third, the juridical link doctrine did not apply in this MDL;[1] as a result, the doctrine did not permit the Plaintiffs to sue on behalf of others with the same injury. *Id.* at 33. Fourth, the named Plaintiffs lacked standing to assert claims on behalf of class members whose claims arise under other states' laws. *Id.* at 36.

Significantly, fifth, the Court determined that the Plaintiffs could not rely on *Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076 (11th Cir. 2019), to support their theory of standing. In

[1] The juridical link doctrine is an exception to the general rule that a plaintiff cannot bring a class action against parties that did not injure the plaintiff. The doctrine applies when "all defendants are juridically related in a manner that suggests a single resolution of the dispute would be expeditious." *La Mar v. H & B Novelty & Loan Co.*, 489 F.2d 461, 466 (9th Cir. 1973).

Debernardis, the Eleventh Circuit determined that the plaintiffs had standing to sue the manufacturers of a supplement that was presumptively "adulterated" under the Federal Food, Drug, and Cosmetic Act ("FDCA"), because the supplement was illegal to sell, *id.* at 1082, 1085 n.6, 1088, and the FDA had warned the manufacturers (before they sold the supplements) that the supplements were illegal to sell. *Id.* at 1082. The Eleventh Circuit "cautioned" courts that its holding was "limited to the specific facts alleged in this case." *Id.* at 1088. In contrast, in this MDL, ranitidine was legal to sell[2] and the FDA never instructed the Defendants to stop selling ranitidine before the FDA requested that the Defendants voluntarily recall the drug. Since ranitidine was legal to sell, the Court determined that the Plaintiffs must rely on other caselaw to support their standing position when they amended their shotgun pleadings. DE 2515 at 43.

The Plaintiffs expanded upon their standing theory during the second round of motions to dismiss. In the Plaintiffs' amended economic class action complaint, the Plaintiffs again alleged that ranitidine was "worthless," "inherently defective and unreasonably dangerous." *See* DE 2837 (referring to ranitidine as "worthless" 1,490 times, "unsafe" 2,630 times, and "dangerous" 1,540 times). In opposition to the Defendants' second round of motions to dismiss for lack of standing, the Plaintiffs argued, "[T]hey purchased ranitidine products. . . . They made these purchases without knowing ranitidine causes cancer. . . . Plaintiffs would not have made these purchases if they had known that it did cause cancer," DE 3429 at 35-36 (emphasis omitted) (citations omitted); June 3, 2021, Hearing Tr. at 152-53, and, critically, had the FDA known that ranitidine turned into NDMA, the FDA would not have allowed ranitidine to be sold. *Id.* at 174. Therefore, the Plaintiffs argued, while ranitidine was technically legal to sell, ranitidine should not have been sold without

[2] The FDA has not banned the sale of ranitidine. June 3, 2021, Hearing Tr. at 175, 225-26.

disclosing its cancer-causing propensity and, consequently, was misbranded when sold and "worthless." *Id.* at 173 (arguing that ranitidine was "defective and misbranded because it turns into and causes a safety defect, it turns into NDMA"); *id.* at 177-81 ("[C]ompared to the cases where the packaging contains less than you bargained for, here you are bargaining for a drug that is going to help you, not hurt you, and what you got was a drug that is going to hurt you, when you could have bought . . . something else."). Because ranitidine had an "undisclosed safety defect," rather than a "purely procedural violation" like in *Debernardis*, the Plaintiffs argued that their case for standing was stronger than the *Debernardis* case. DE 3429 at 37-38. Their case, the Plaintiffs posited, was more like *In re Aqua Dots Products Liability Litigation*, 654 F.3d 748 (7th Cir. 2011), in which parents had standing to sue the manufacturer of a toy that could harm their children, even though their children were unharmed, because the parents would not have purchased the toy had they known of the toy's safety defect. DE 3429 at 38; June 3, 2021, Hearing Tr. at 153-54.

In summary, to prove that the Plaintiffs had suffered an economic injury-in-fact and therefore had standing to sue, they argued that ranitidine: could cause cancer; was unsafe; was misbranded since its label failed to disclose that the product was unsafe; should not have been sold; and, as a result, was worthless. The Court refers to this standing theory as the Plaintiffs' "misbranding theory" because it aligns with the FDCA's prohibition against the sale of "misbranded drugs," as that term is defined in the FDCA. *See* 21 U.S.C. §§ 331, 352(j). Importantly, all of the Plaintiffs' standing arguments rested on this misbranding theory.

The Plaintiffs never made any other arguments in support of their standing to sue during the multiple rounds of motions to dismiss. The Plaintiffs, for example, did not contend that ranitidine's value was something greater than zero but less than the purchase price they paid for it.

June 3, 2021, Hearing Tr. at 190 (committing to their position that ranitidine was worthless and not worth less). Similarly, the Plaintiffs did not contend that ranitidine causes any harm other than cancer. *See id.* at 213-14 (answering "no" when the Court asked, "in alleging your claim for medical monitoring, are you relying upon anything other than Ranitidine's propensity to form NDMA?). And, the Plaintiffs did not contend that ranitidine was illegal to sell for any reason other than its cancer-causing propensity or the presence of NDMA at levels above the FDA's acceptable daily intake level ("ADI").

The Plaintiffs only raised and, thus, the Court's early attention and rulings on standing were singularly focused on the Plaintiffs' misbranding theory. Based on this theory, the Court determined that the Plaintiffs had standing to proceed through the motion to dismiss stage by alleging an economic injury-in-fact based on the purchase of a misbranded, unsafe, and worthless product (ranitidine) that they would not have purchased had its label disclosed its cancer-causing propensity. DE 3720 at 51-53. The Court reasoned that, if a product performs as advertised (and therefore is not deemed worthless under applicable caselaw) but also causes cancer, the product could have been misbranded and should not have been sold. Because the Plaintiffs pled that ranitidine could have been misbranded and should not have been sold, the Court determined, that pursuant to the reasoning in *Debernardis*[3] and *Aqua Dots*, the Plaintiffs suffered an injury-in-fact when they purchased ranitidine. Therefore, ultimately, the Plaintiffs had standing to pursue their claims stated in the Second Amended Consolidated Economic Loss Class Action Complaint ("SAELC").

[3] The Court partially relied on *Debernardis* in its order on the second round of motions to dismiss, in contrast to its earlier order distinguishing *Debernardis*. This is because in the Court's later discussion of *Debernardis*, the Court focused on the Plaintiffs' allegations of a misbranded product that should not have been sold, while in its earlier discussion, it focused on the fact that at all points at time, and even to this very day, ranitidine remains legal to sell.

Despite its ruling on standing at the motion to dismiss stage of the proceedings, the Court informed the parties that it would return to the issue of standing when the evidentiary record in this MDL was more developed. The Court explained that "[t]he Court is free, and in fact obligated, to consider the question of standing *sua sponte* at each stage of the litigation." DE 3720 at 53. "Discovery may reveal additional facts bearing on the Plaintiffs' standing (or lack thereof), and the Plaintiffs must back up the allegations that they rely on for standing with evidentiary support in the record." *Id.*; *cf.* DE 1980 at 19-20 ("After discovery, the evidentiary demands on a plaintiff go up, and the Court may insist that a litigant train its sights on the discrete defendants responsible for her injuries."). The Court indicated that it would consider the issue of standing again should the Plaintiffs' misbranding theory prove inapplicable because the Plaintiffs could not prove that ranitidine was in fact misbranded.

After the motion to dismiss stage, the parties and the Court proceeded to the *Daubert* stage of the MDL, at which time the Plaintiffs submitted their strongest evidence to prove that ranitidine could cause the Designated Cancers.[4] The Court determined that the Plaintiffs' scientific evidence was unreliable, *see* DE 6120, and as a result, the Plaintiffs lack reliable evidence that ranitidine causes Designated Cancers, as well as Non-Designated Cancers (since the Plaintiffs did not present any evidence of Non-Designated Cancers), *see* DE 6299. Given the Plaintiffs do not have any evidence of other cancers with which to support their class action claims—the Plaintiffs do not have any reliable evidence of cancer causation.[5]

[4] The Designated Cancers are bladder, esophageal, gastric, liver, and pancreatic cancers.

[5] As explained in the Court's First Order to Show Cause, the Court's *Daubert* ruling applies to the class action claims, in addition to the personal injury claims, for all of the reasons outlined on pages 11-20 of the Court's order at docket entry 6303. Also, the Plaintiffs concede that the *Daubert* ruling applies to their class action claims. DE 6484 at 1. For both of these reasons, the *Daubert* ruling applies to the class action claims.

II. The Effect of the Court's *Daubert* Ruling on the Plaintiffs' Misbranding Theory

In light of the *Daubert* ruling, the parties agreed that the Court should not proceed with briefing on class certification. In the Class Plaintiffs' Motion to Stay Class Proceedings Pending the Outcome of Appellate Proceedings on this Court's *Daubert* and Summary Judgment Rulings [DE 6148], the Plaintiffs moved the Court to stay class proceedings until they completed their appeals of the *Daubert* ruling. DE 6148 at 7. The Defendants, in response, requested that the Court enter final judgment for them on the class action claims because both sets of the Plaintiffs' class action claims, the medical monitoring and economic loss class action claims, are no longer viable as pled. DE 6227 at 26.

The Plaintiffs concede that their medical monitoring class action claims are no longer viable, but they assert that they still can pursue their economic loss class action claims. In the following section, the Court briefly analyzes the medical monitoring class action claims, before turning to the Plaintiffs' economic loss class action claims—recounting the Court's order to show cause process, the responses elicited during this process, and the Court's conclusion as to the viability of these claims.

A. Medical Monitoring Class Action Claims

The Plaintiffs concede that their medical monitoring class action claims are not viable. DE 6254. Generally, to prevail on a medical monitoring claim, a plaintiff must prove

> (1) the defendant's negligence (2) caused (3) the plaintiff to become exposed to a hazardous substance that produced, at least, subcellular changes that *substantially increased the risk of serious disease*, illness, or injury (4) for which an effective medical test for reliable early detection exists, (5) and early detection, combined with prompt and effective treatment, will significantly decrease the risk of death or the severity of the disease, illness or injury, and (6) such diagnostic medical examinations are reasonably (and periodically) necessary, in conformance with the

> standard of care, and (7) the present value of the reasonable cost of such tests and care as of the date of the filing of the complaint must be established.

In re Nat'l Hockey League Players' Concussion Inj. Litig., 327 F.R.D. 245, 261 (D. Minn. 2018) (emphasis added). A plaintiff must show an increased risk of disease to sustain a medical monitoring claim. Therefore, in this MDL, an "increased risk of cancer is a predicate of medical monitoring claims." Dec. 14, 2020, Hearing Tr. at 149; June 3, 2021, Hearing Tr. at 210-12; *see also id.* at 146 ("We plausibly allege that the increased risk of disease warrants diagnostic testing that is reasonably necessary and different from routine medical care.").

The Court's *Daubert* ruling directly impacts the Plaintiffs' ability to prove that they have an increased risk of cancer. In the Motion to Stay, the Plaintiffs acknowledge that the Court's *Daubert* ruling applies to their class action claims and, consequently, "[a]bsent reversal of the general causation *Daubert* ruling, . . . the Court's rulings likely undermine the availability of medical monitoring claims." DE 6148 at 4. Further, in their Reply, the Plaintiffs acknowledge that affirmance of the *Daubert* ruling "would likely spell the death knell of the medical monitoring claims," DE 6254 at 2, because the Plaintiffs lack reliable evidence with which to prove that the Plaintiffs have an increased risk of cancer and cannot prevail on their medical monitoring class action claims without such evidence. The Plaintiffs did not argue in their briefing that their medical monitoring class actions claims are viable, thus conceding that these claims are not viable. And, the Court agrees with the Plaintiffs that these claims are not viable for all of the reasons outlined in the Court's First Order to Show Cause [6484].[6] DE 6484 at 5-6. The significance of the Court's *Daubert* ruling is that the Plaintiffs do not have proof that they have an increased risk

[6] In order to resolve the Plaintiffs' Motion to Stay, the Court issued two orders to show cause. The Court explains the procedural history of the orders to show cause and the parties' responses to the orders in Section III.A, *infra*.

of cancer and, thus, have no basis to request periodic testing for cancer through medical monitoring class action claims.

B. Economic Loss Class Action Claims

In contrast, the Plaintiffs do not concede that, in light of the *Daubert* ruling, their economic loss class action claims lack viability. They argue that neither safety nor cancer causation are elements of economic loss class action claims and therefore the Court's *Daubert* ruling does not specifically foreclose the Plaintiffs' ability to prove those claims. *See* DE 6148 at 4. Stated another way, whereas the Court's *Daubert* ruling directly impacted an element of medical monitoring—a substantial increase in the risk of disease—the Court's *Daubert* ruling does not directly impact any element of the economic loss class action claims.

The Plaintiffs argue that they can proceed with their economic loss class action claims, based not on their previously articulated misbranding theory (relating to safety, cancer, and worthlessness) but on new[7] arguments centered on an "adulteration" theory. *Id.* In this section, the Court reviews the viability of the Plaintiffs' misbranding theory before turning to the Plaintiffs' new adulteration theory.

1. The Plaintiffs Do Not Defend Their Misbranding Theory.

The Plaintiffs do not defend their previously held misbranding theory, even though the Defendants argue that this theory is no longer viable. The Defendants argue that every count in the SAELC relies on allegations that the NDMA in ranitidine could cause cancer consistent with the Plaintiffs' misbranding theory, and, now that the Plaintiffs do not have evidence of cancer causation, the Plaintiffs cannot succeed in proving the claims stated in the SAELC. DE 6227 at 13.

[7] The Plaintiffs' master complaints contained a small number of allegations pertaining to adulteration, but the Plaintiffs' adulteration-based standing theory is, as explained in this Order, new.

Though the Plaintiffs could have defended the viability of their misbranding theory in response to this argument, the Plaintiffs do not defend this theory in their briefing on the Motion to Stay, their response to the Court's First Order to Show Cause, and their response to the Court's Second Order to Show Cause [DE 6639].

2. *Misbranding Requires Evidence that Ranitidine is Unsafe.*

The Plaintiffs may have chosen not to defend their misbranding theory because the theory fails without proof that ranitidine is unsafe. The Plaintiffs pled that ranitidine was misbranded because its label failed to disclose that it could cause cancer; every claim pled in the SAELC rests on the allegation that the NDMA in ranitidine could cause cancer. *See* DE 3325 at 14-15. Without proof of cancer causation, the Plaintiffs cannot succeed in proving their claims as pled.

In addition, to succeed on a misbranding claim in general, a plaintiff must prove that the product is unsafe under the FDCA. *See* Brief for the United States as Amicus Curiae Supporting Petitioner at 6, 23-25, *Mutual Pharm. Co. Inc. v. Bartlett*, 570 U.S. 472 (2013) (No. 12-142), 2013 WL 314460, at *6, *23-25 ("A drug is misbranded if, *inter alia*, it is 'dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.'"); *United States v. 62 Packages More or Less of Marmola Prescription Tablets*, 48 F. Supp. 878, 887 (W.D. Wis. 1943), *aff'd*, 142 F.2d 107 (7th Cir. 1944) ("The purpose of the [FDCA] is to protect the public . . . . It was enacted to make self-medication safer and more effective, and to require that drugs moving in interstate commerce be properly labeled so that their use as prescribed may not be dangerous to the health of the user."); 21 U.S.C. § 352(a)(1), (j) ("If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."); 21 U.S.C.

§ 321 ("If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account . . . the extent to which the labeling or advertising fails to reveal facts . . . material with respect to consequences which may result from the use."). After the Court's *Daubert* ruling, the Plaintiffs lack reliable evidence to prove that ranitidine is unsafe and, therefore, their misbranding claims cannot succeed. For these reasons, the Plaintiffs' misbranding theory is not viable after the Court's *Daubert* ruling.

3. The Plaintiffs Effectively Concede Misbranding Is No Longer Viable.

The Plaintiffs also effectively concede that their misbranding theory is no longer viable when they concede that their medical monitoring class action claims are not viable because they do not have reliable evidence of cancer causation. The Plaintiffs cannot, on the one hand, acknowledge that are unable to prove they have a significantly increased risk of cancer, while on the other hand claim that they can prove that ranitidine is unsafe and dangerous. Thus, in conceding their medical monitoring class action claims, the Plaintiffs concede that the Court's *Daubert* ruling precludes them from pursuing all claims based on the allegation that the NDMA in ranitidine can cause cancer. This includes the economic loss class action claims proceeding under a misbranding theory.

The Court concludes that the Plaintiffs' misbranding theory fails because, in addition to the Plaintiffs' concessions, the Plaintiffs lack evidence to prove that the NDMA in ranitidine could cause cancer. Because the Plaintiffs' theory of standing based on misbranding is the only theory that the Plaintiffs have relied on in over three years of litigation, the Plaintiffs' economic loss class

action claims should be dismissed for lack of standing. In the alternative, the Court analyzes the viability of the Plaintiffs' new adulteration theory of standing.

III. The Plaintiffs Pivot to an Adulteration Theory

Instead of defending their misbranding theory of standing, the Plaintiffs pivot to arguments based on a different theory, adulteration. As a threshold matter, the Plaintiffs' new standing theory contradicts the Plaintiffs' prior representations to this Court. *See* DE 3682 at 184 ("[I]f ultimately the proof showed that the drug was not dangerous, or did not create NDMA, absolutely, I think we lose."[8] (referring to standing)).

Putting aside the Plaintiffs' prior representations on standing during the motion to dismiss stage of the MDL, the Plaintiffs relied on their misbranding theory, arguing that ranitidine could cause cancer, was therefore unsafe and, since it was unsafe, it should not have been sold and was worthless. The Plaintiffs clearly pled and clearly argued each of these points. In contrast, the Plaintiffs neither clearly pled nor clearly argued an adulteration theory for standing. When the Defendants twice moved to dismiss the Plaintiffs' economic loss class action claims for lack of standing, both times, it was incumbent on the Plaintiffs to raise their adulteration theory if that theory was an independent basis for the Court to deny the Defendants' motions to dismiss, but they did not do so.[9]

In the absence of a clearly pled (and argued) adulteration standing theory, the Court afforded the Plaintiffs multiple opportunities to explain their new theory. In this section, the Court

[8] Twice the Court presented this quote to the Plaintiffs, and in each instance the Court asked the Plaintiffs to specifically respond to the position the Plaintiffs communicated to the Court in the quotation. Both times the Plaintiffs did not acknowledge the quotation in their response to the Court's Orders to Show Cause.

[9] If the Plaintiffs had pled a viable adulteration theory in their complaint, as the Plaintiffs now contend, and the Defendants made no arguments about the adulteration theory in their motions to dismiss, then the Defendants' oversight as to the existence of an independent basis for the Plaintiffs' standing was an independent basis for the Court to deny the motions.

sets forth the steps it took, through two orders to show cause, to elicit a response from the Plaintiffs about their adulteration theory. The Plaintiffs have not adequately done so.

A. Procedural History of Court's Order to Show Cause Process

The Court entered a First Order to Show Cause under Federal Rule of Civil Procedure 56(f) outlining its preliminary observations of the Plaintiffs' adulteration theory, as informed by the Plaintiffs' Motion to Stay briefing. The Court explained that it understood the Plaintiffs' adulteration theory to proceed as follows: under 21 U.S.C. § 331, the Defendants had a duty not to manufacture and sell an adulterated drug; ranitidine was an adulterated drug because ranitidine contained a contaminant carcinogen, NDMA; therefore, when the Defendants manufactured ranitidine, which contained NDMA, the Defendants violated their duty under the FDCA; and, in doing so, the Defendants also violated a state-law duty not to sell products with trace amounts of carcinogens without a warning label. Because this was a novel theory, in its First Order to Show Cause, the Court asked the Plaintiffs to explain this theory and to answer questions about it to permit the Court to evaluate whether the Plaintiffs have standing to pursue their theory and whether the Plaintiffs' adulteration theory otherwise is viable. The Plaintiffs responded, DE 6589, and the Defendants replied, DE 6624.

In the Class Plaintiffs' Response to the Court's Order to Show Cause [DE 6589], the Plaintiffs not only failed to clearly articulate their adulteration theory, but also their responses to the Court's questions were inconsistent and incomplete. For instance, in the Response, the Plaintiffs claim that, because ranitidine contained NDMA, ranitidine products were "adulterated and not made in a cGMP-compliant manner to assure they possessed the quality and identity represented, and were fit for their intended purpose." DE 6589 at 9, 16. Simultaneously, the

Plaintiffs also claim that their adulteration theory is based on ranitidine's label, meaning, in theory, the Defendants could cure their adulteration problem under federal law by changing ranitidine's label. *Id.* at 11-12. Yet the Plaintiffs do not explain how the Defendants could cure ranitidine's adulteration problem (*i.e.*, ranitidine contained NDMA) with a label change, which would do nothing to correct the contamination.

Due to inconsistencies like this one and the Court's other remaining questions, the Court issued a Second Order to Show Cause, again under Rule 56(f), ordering the Plaintiffs to respond to the Court's unanswered questions, to explain why ranitidine was worthless, and to come forward with citations to their pleading or evidence to support their position. In Class Plaintiffs' Response to the Court's Second Order to Show Cause [DE 6676], the Plaintiffs provided no additional citations to their pleadings or additional insight into their adulteration theory. DE 6676 at 2. Further, the Plaintiffs failed to present any evidence to support their adulteration theory. From these two rounds of responses, it was clear to the Court that, whatever the Plaintiffs' adulteration theory is, it is not the theory that the Plaintiffs had advanced throughout the duration of this MDL (that ranitidine could cause cancer; it was therefore unsafe; and, since it was unsafe, it should not have been sold and was worthless).

B. Matters Resolved in the Order to Show Cause Process

Despite the Plaintiffs' failure to clearly articulate their adulteration theory or support it with evidence from the record, the Plaintiffs' briefing did provide the Court with sufficient information to resolve several legal issues that bear on the viability of Plaintiffs' economic loss class action claims under an adulteration theory. In the following section, the Court analyzes these issues related to the Plaintiffs' adulteration theory.

1. *The Plaintiffs Have Not Pled and Also Have Abandoned the Position that Ranitidine Was Unsafe for Any Reason Other than Cancer.*

First, the Plaintiffs have not pled that ranitidine is "unsafe" for reasons other than cancer causation. The word "cancer" appears in the SAELC 1,636 times. This entire MDL is about a carcinogen, NDMA, found in ranitidine. During the second round of motions to dismiss, the Plaintiffs argued that their claims relied solely on ranitidine's propensity to form NDMA; their claims did not rest on other carcinogens; thus, the Court concluded that the Plaintiffs' claims did not relate to harms other than cancer. *See* DE 3682 at 213-14. In both Orders to Show Cause, the Court ordered the Plaintiffs to "explain to the Court their theory of injury in fact, if their theory is an injury other than cancer, and inform the Court where in their pleadings they have pled such a theory and in what filings they have pursued such a theory." DE 6639 at 4. The Plaintiffs did not respond; they did not claim that ranitidine was unsafe because it caused a harm other than cancer. Moreover, because the Plaintiffs have not pled that ranitidine is unsafe for a reason other than cancer, because the Plaintiffs confirmed to the Court at oral argument that their claims were focused on cancer as the only potential harm in this MDL, and because of the Plaintiffs' concession on the viability of their medical monitoring claims (as discussed above in Section II(B)(3)), the Plaintiffs have not advanced, and they also have abandoned, the contention that ranitidine is unsafe on account of any harm apart from cancer.

2. *The Plaintiffs Have Not Pled and Also Have Abandoned the Position that Ranitidine Was "Worth Less."*

Second, the Plaintiffs have not pled and also have abandoned the contention that ranitidine was "worth less" (two words), instead of "worthless" (one word). During the second round of motions to dismiss, the Plaintiffs made this point on the record, at the Defendants' prompting:

> MS. COHAN: I think both are being argued, the worthless and worth less, but I think Plaintiffs concede both are not pled. Here they have merely pled Plaintiffs would not have purchased the product if they had been aware of the alleged cancer risk. In addition, in their briefing throughout they have said that the product is worth zero dollars. So, I do think that, despite that argument, that is not something they have followed through on.
>
> THE COURT: Well, I guess you do argue it at 3429 at page 36. Are you putting that forth as a theory, the worth less, two words? I know you are saying it is subsumed, but I think the Defense should know what you are arguing right now.
>
> MS. FEGAN: Your Honor, **when I think of worth less as two words, I think of drug price premium cases, and I will commit this is not a price premium case,** this is not about a slight overcharge and what it would have cost versus a competitor. We are talking about a drug that was recalled because it causes cancer, and in that context **we are saying it as one word, it is worthless**.

DE 3682 at 190 (emphasis added). The Court relied on the Plaintiffs' representations when it rendered its earlier decision on standing; the Court undertook no analysis of an argument that ranitidine could have some value greater than zero because the Plaintiffs did not advance such a proposition.

In the order to show cause process, the Court presented the Plaintiffs with two opportunities to persuade the Court that they had not abandoned the contention that ranitidine was worth less. In response to the First Order to Show Cause, the Plaintiffs argued that they did not abandon this position because they had not yet submitted their class certification motion and expert reports. DE 6589 at 12. In the Second Order to Show Cause, the Court ordered the Plaintiffs to "explain, in light of their commitment on the record that this is not a drug price premium case and their subsequent briefing filed in this case, how they have not abandoned the contention that ranitidine was worth less." DE 6639 at 3. In response, the Plaintiffs did not offer anything further. Based on this record, the Court concludes that (i) the Plaintiffs have not pled that ranitidine could have a value greater than zero; (ii) the Plaintiffs clarified their pleading and represented to the Court that

they had not pled that ranitidine could have a value greater than zero; and (iii) the Plaintiffs abandoned the contention that ranitidine is worth less (some value greater than zero) and failed to persuade the Court otherwise in their responses to the Orders to Show Cause.

In summary, the Plaintiffs' standing theory, a misbranding theory, rests on the contention that ranitidine could cause cancer, it was therefore unsafe, and, since it was unsafe, it should not have been sold as a misbranded product and was worthless with a value of zero. Based on these allegations, the Court found that the Plaintiffs had standing to pursue their economic loss class action claims. Now, after the Court's *Daubert* ruling and the order to show cause process, the Plaintiffs' misbranding theory is no longer viable. The Plaintiffs have no evidence of cancer causation; they have no allegation that ranitidine is unsafe for some other reason; they have produced no evidence that ranitidine is unsafe for some other reason; they have (through their clarifications and representations to the Court) not pled that ranitidine has some partial, non-zero value; and, the Plaintiffs' lack any basis—through pleadings or evidence—to advance the proposition that ranitidine is worthless, with a value of zero, even though it performed as advertised and even though they have no evidence it causes harm.

IV. Viability of the Plaintiffs' Adulteration Theory Under the SAELC

The only question remaining is whether the Plaintiffs can proceed with their new standing theory based on adulteration under the SAELC. The Court makes certain observations about the Plaintiffs' adulteration theory. First, this theory does not rely on the allegation that ranitidine is unsafe for some reason other than cancer; and second, this theory does not rely on the allegation that ranitidine was worth less, instead of worthless.

The Plaintiffs' adulteration theory is incompatible with the misbranding theory pled throughout the SAELC. For example, the Plaintiffs' misbranding theory posited that even though ranitidine performed as advertised (*e.g.* it alleviated heartburn), it was still a worthless product because it caused cancer. Under the Plaintiffs' new theory, if ranitidine performed as advertised, how can it be worthless (with a value of zero), given that the Plaintiffs have no reliable evidence that the drug was unsafe? The Court attempted to elicit an answer from the Plaintiffs on this question in response to the First and Second Orders to Show Cause. In response, the Plaintiffs failed to explain why ranitidine is worthless, instead noting that they can

> introduce a variety of evidence, such as: (1) their deposition testimony regarding what **they** would pay for Zantac (nothing); (2) expert testimony regarding the safety, **or perceived safety**, of Zantac in general (as opposed to expert testimony regarding whether Zantac causes the five designated cancers); (3) expert testimony regarding the economic value of Zantac, including expert testimony regarding **how consumers consider** dangers that are less rigorously proven than what a court would accept for purposes of *Daubert*; (4) evidence regarding the FDA's recall of Zantac (likewise applying precautionary standards lower than that which passes muster under *Daubert*); and (5) Defendants' unwillingness to sell the product knowing it degrades into NDMA.

DE 6589 at 14 (emphasis added). The Plaintiffs' position appears to be that instead of proving that ranitidine **was objectively worthless**, they could prove that a Plaintiff **believed** it was worthless. In other words, the Plaintiffs' position is that they can establish economic injury not because of an objective criterion, but because of a consumer's **subjective belief**. This position is contrary to well established caselaw. *See, e.g.*, *Koronthaly v. L'Oréal USA, Inc.*, 374 F. App'x 257, 259 (3d Cir. 2010); *In re Johnson & Johnson Talcum Powder Prods. Mktg. Sales Pracs. & Liab. Litig.*, 903 F.3d 278, 281 (3d Cir. 2018); *Shaulis v. Nordstrom, Inc.*, 865 F.3d 1, 12 (1st Cir. 2017) (concluding that the plaintiff lacked standing because the plaintiff failed to identify

"anything objective" for which she had bargained and did not receive from her purchase, instead identifying only her "subjective belief as to the nature of the value" of her purchase).

Regardless of the basis for the Plaintiffs' measurement of the value of ranitidine, the Plaintiffs have provided no citations to the SAELC for the proposition that they previously pled that ranitidine is worthless for some reason other than cancer causation and, as discussed above, they have abandoned (and have not pled) the proposition that ranitidine could be worth more than zero, worth less. The Plaintiffs also previously represented to the Court that they would lack standing if ranitidine did not cause cancer:

> THE COURT: For example, am I understanding what you just said to say that perhaps, once we get into individual Plaintiff discovery and we learn, let's just say hypothetically, gee, the risk was not so great, it wasn't so harmful, or it wasn't as harmful as alleged, would that bear -- should that bear on the Court's consideration of standing, and would that be the more -- if yes, would that be a reason why the Court would want to consider that at a later point, or does that have nothing to do with the analysis of standing?
>
> MS. FEGAN: Your Honor, if ultimately the proof showed that the drug was not dangerous, or did not create NDMA, absolutely, I think we lose. . . .

DE 3682 at 184.

Because neither the SAELC nor the Plaintiffs' prior representations to the Court are compatible with an adulteration theory, the Plaintiffs' pursuit of that theory may only be viable through amendment. Yet, the Plaintiffs cannot now amend their SAELC to restate their economic loss class action claims under a new adulteration standing theory for two reasons. First, the Plaintiffs committed to the position that, because the SAELC is compatible with their adulteration theory, they neither needed nor wanted an amended pleading. *See* DE 6484 at 18; DE 6639 at 5; DE 6676 at 10.

Second, and in the alternative, even if the Plaintiffs were to request leave to amend, the Court would deny the Plaintiffs leave to file a fourth economic loss complaint for all of the reasons set forth in Brand Defendants' Reply to the Court's Order to Show Cause Why the Economic Loss Complaint Is Not Subject to Dismissal or Summary Judgment [DE 6624]. This MDL began in 2020, discovery began shortly thereafter, the Plaintiffs first filed their economic loss class action claims in 2020, their second pleading in early 2021, and their third and operative pleading, the SAELC, in late 2021. The Plaintiffs have had years to plead a theory of recovery (or standing theory) that is not based on cancer or safety and have not done so. Therefore, permitting amendment at this time is unwarranted and would be unfairly prejudicial to the Defendants, who would be surprised to have to defend against an entirely new standing theory, premised on a new theory of recovery that does not rely on cancer, over three years into this MDL.

The Court's denial of leave to amend could end the Court's inquiry into standing; the Plaintiffs' prior misbranding theory of standing fails; the SAELC does not support the Plaintiffs' new adulteration theory; and, the Court will not permit yet another amendment. Yet, in the alternative, even if the Court were to permit the Plaintiffs to amend the SAELC and file a fourth amended economic loss class action complaint, the Court concludes that the Plaintiffs still would lack standing to pursue their claims under their new theory for the reasons set forth below.

A. The Plaintiffs Improperly Rely on the FDA's ADI to Establish Adulteration

The Plaintiffs' adulteration theory of standing is not viable because it improperly relies on the FDA's ADI. The FDA established the ADI for NDMA in ranitidine around 2019. The Plaintiffs claim that ranitidine was adulterated "as determined by Congress because it was sold with amounts of NDMA higher than level permitted by Congress or **under its delegation of**

authority to the FDA." DE 6254 at 9 (emphasis added). In other words, ranitidine was adulterated because it contained NDMA at levels exceeding the FDA's ADI; since it was adulterated, it was worthless; and since ranitidine was worthless, the Plaintiffs suffered an economic injury-in-fact when they purchased it for a value greater than zero, without knowing that it contained NDMA.

One of the problems with this argument, though, is that many of the named Plaintiffs (and quite possibly all of them) allege that they purchased ranitidine before 2019, the year the FDA established the ADI, and the Plaintiffs do not explain whether the ADI applies retroactively, rendering all ranitidine ever sold adulterated, or prospectively, rendering only ranitidine sold after the establishment of the ADI potentially adulterated. The Court asked the Plaintiffs in the First and Second Orders to Show Cause to address the retroactivity of the ADI. *See* DE 6484 at 20; DE 6639 at 7. In response, the Plaintiffs provided no argument or authority to support the contention that the ADI applies retroactively, despite the Court twice directly prompting them to do so.[10] Without any argument or authority to the contrary, the Court cannot conclude that the ADI applies retroactively. Consequently, the Court is unpersuaded that the Plaintiffs can state a viable adulteration theory of standing based on the ADI for NDMA in the years before the FDA established the ADI.

B. Ranitidine Adulterates Itself Through an Alleged Design Defect

The Plaintiffs cannot state adulteration claims under the FDCA because they have proceeded in this MDL on the grounds that ranitidine self-adulterates. The Plaintiffs' arguments and the record evidence in this MDL supports the position that ranitidine self-adulterates, meaning ranitidine, when manufactured, stored, and distributed in compliance with all FDA regulations,

[10] The Plaintiffs presumably rely on the FDA's ADI because, were they to try to prosecute claims based on some lesser standard, the Plaintiffs' claims likely would be pre-empted by federal law. *See infra* note 11.

will nonetheless break down into NDMA because of its inherent molecular design. Yet the Plaintiffs contend that claims based solely on the presence of NDMA in ranitidine are state law claims that parallel federal adulteration law and are not design defect claims.

First, since these claims are based on the inherent design of ranitidine, and since ranitidine self-adulterates, the Court views the claims based on the presence of NDMA in ranitidine as design defect claims. In both Orders to Show Cause, the Court asked the Plaintiffs to inform the Court whether they could state adulteration claims (meaning state law claims that parallel federal adulteration law), rather than design defect claims, based on the presence of NDMA in ranitidine and the record evidence in this MDL. *See* DE 6484 at 22; DE 6639 at 8-9. In response to the Court's question in the First Order to Show Cause, the Plaintiffs argued that they could state adulteration claims based on the NDMA in ranitidine "because federal law did not require that Zantac contain NDMA." DE 6589 at 17. In response to the same question in the Second Order to Show Cause, the Plaintiffs argued "whether Zantac self-adulterates – and whether the Defendants knew about it and yet did nothing – is a question of fact for the jury." DE 6676 at 12. These responses do not persuade the Court that the FDCA's prohibition against the sale of adulterated products was intended to prohibit the sale of defective products that self-contaminate and cannot be decontaminated through better manufacturing, better transportation, etc. Stated simply, the Defendants did not contaminate ranitidine with NDMA by including NDMA in the manufacturing process—ranitidine contaminated itself by the nature of its very design. In this MDL, since nothing short of changing the ranitidine molecule could prevent ranitidine from forming NDMA,

the claims that the Plaintiffs bring solely based on the presence of NDMA in ranitidine are design defect claims, not adulteration claims.[11]

Second, even if the Plaintiffs are able to state adulteration claims based on the presence of NDMA in ranitidine alone, the Court is unpersuaded that the Defendants could cure the adulteration with a label change, as the Plaintiffs implicitly contend. When a product is adulterated because it contains an impurity, the Court can understand how a defendant may be able to cure the adulteration problem by removing the impurity; but the Court cannot understand how a defendant could cure the problem under the FDCA—the contamination—by changing the product's label. Yet one area in which the Plaintiffs are clear is that their adulteration theory is based on ranitidine's label. DE 6589 at 12. The Plaintiffs' adulteration theory contends that ranitidine's labeling was deceptive, that the Defendants could have and should have changed ranitidine's label, so, presumably, changing the label would have cured ranitidine's adulteration problem.

The Court asked the Plaintiffs in the First and Second Orders to Show Cause to "provide authority for the proposition that a Defendant manufacturer may comply with state law (as well as federal law) if the Defendant discloses the impurity on its label in lieu of removing the impurity" and "any instance in which the FDA classified a drug as adulterated but, because the adulteration was subsequently disclosed on a label, the drug ceased to be adulterated." DE 6484 at 21-22; DE 6639 at 8. The Plaintiffs did not respond to these questions, though they twice had the opportunity

[11] Because the Plaintiffs' theory of recovery better fits the federal definition of a design defect theory, rather than an adulteration theory, the Plaintiffs also likely cannot survive a federal pre-emption analysis of their economic loss class action claims, which are all brought under state law. To survive a federal pre-emption analysis, a plaintiff must be able to point to a federal-law duty that the defendant allegedly breached that is parallel to the state-law duty that the defendant allegedly breached. The Court invited the Plaintiffs in both Orders to Show Cause to explain to the Court the federal-law and state-law duties that the Defendants allegedly breached and how these duties are parallel. However, the Plaintiffs did not identify the state-law duties breached, so the Court was unable to conduct a pre-emption analysis of the Plaintiffs' economic loss class action claims.

to do so. Consequently, the Court is not persuaded that the Defendants in this case could cure their adulteration problem under the FDCA, if it existed, by changing ranitidine's label. And since the Defendants could not fix the problem with a label change—only a design change—the Court is not persuaded that the Plaintiffs could plead a viable adulteration theory in any amended pleading.

V. The Plaintiffs Did Not Meet Their Standing Burden

The party invoking federal jurisdiction has the burden of proving that he or she has standing to pursue his claims in federal court. *See FW/PBS, Inc. v. Dallas*, 493 U.S. 215, 231 (1990). To have standing, the party "must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Debernardis*, 942 F.3d at 1083 (quoting *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016), *as revised* (May 24, 2016)). Each standing element must be supported "in the same way as any other matter on which the plaintiff bears the burden of proof, *i.e.*, with the manner and degree of evidence required at the successive stages of the litigation." *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). Therefore, the party invoking federal jurisdiction "must 'set forth' by affidavit or other evidence 'specific facts'" to support their claim of standing at the summary judgment stage of the litigation. *Id.*

In this MDL, the Plaintiffs have the burden to prove that they have standing to pursue their economic loss class action claims, which they have not met. The Court issued two Orders to Show Cause under Rule 56(f), requiring the Plaintiffs to point to where in the SAELC they had pled their adulteration theory, to put forward evidence to prove injury-in-fact, and to explain their position on standing. The Plaintiffs either could have identified paragraphs in the SAELC to show how they had pled an adulteration theory that could succeed in light of the record evidence in this MDL,

or requested to amend the SAELC to establish standing based on an adulteration theory. But the Plaintiffs did neither.[12] *See* DE 6589 at 11-13 (failing to cite to any paragraphs in the SAELC when arguing that they have standing in response to the First Order to Show Cause); DE 6676 at 7-9 (citing to paragraphs in the SAELC, without explaining how these claims can succeed based on the record evidence, their abandonment of the position that ranitidine is unsafe for some reason other than cancer, and their abandonment of the position that the value of ranitidine was ever greater than zero, when arguing that they have standing in response to the Second Order to Show Cause). The Plaintiffs also failed to present any evidence in response to the Orders to Show Cause, as the Court ordered. Lastly, the Plaintiffs did not answer the Court's specific questions about their standing theory, including why ranitidine was worthless without evidence of harm. For these reasons, the Plaintiffs did not meet their burden of persuasion, and the Court concludes that the Plaintiffs' adulteration theory does not confer standing on the Plaintiffs. In the next section, the Court analyzes whether the Plaintiffs have standing for any reason other than an adulteration theory of standing.

VI. Application of Standing Caselaw to the Plaintiffs' Adulteration Theory

The injury-in-fact analysis in this MDL begins with *Debernardis*. In *Debernardis*, plaintiffs who had purchased presumptively adulterated dietary supplements filed state-law claims and claims for common law fraud and unjust enrichment against the manufacturer and the exclusive distributor of the supplements. 942 F.3d at 1080-82. The Eleventh Circuit concluded

[12] The Plaintiffs did not respond to the Court's questions about other topics as well. For instance, in the First and Second Orders to Show Cause, the Court cited caselaw standing for the proposition that a plaintiff cannot state claims based on trace amounts of contaminants unconnected to human harm. The Court also asked the Plaintiffs to provide the Court with caselaw to the contrary, DE 6484 at 19-20; DE 6639 at 7, but the Plaintiffs did not put forward persuasive caselaw in response to support their position that the Defendants violated state-law duties by manufacturing ranitidine with trace amounts of NDMA.

that the plaintiffs had standing to pursue these claims, at least through the motion to dismiss stage of the litigation, because "the plaintiffs were deprived of the entire benefit of their bargain" when they purchased presumptively adulterated and unsafe supplements. *Id.* at 1082, 1085 n.6, 1088. The concurrence pointed out that, at summary judgment, each plaintiff would need to prove "[w]hy was the product worthless to each of them." *Id.* at 1090 (Sutton, J., concurring).

In so concluding, the Eleventh Circuit appeared to limit its standing holding to economic loss claims stemming from the purchase of unsafe products. The Eleventh Circuit explained as *dicta* that its holding did not mean that "any consumer who purchased a product that could not legally be sold for any reason will have acquired a worthless product and thus have standing to sue." *Id.* at 1088. And, to explain what its holding did mean, the Eleventh Circuit cited *Franz v. Beiersdorf, Inc.*, 745 F. App'x 47 (9th Cir. 2018), another case in which defendants sold presumptively unsafe products, and *Aqua Dots*, a case in which defendants sold unsafe products, the specific facts of which are recounted above in Section I.

In contrast to the standing analysis in product safety cases, such as *Debernardis* and *Aqua Dots*, a plaintiff does not have standing to sue a defendant merely because of buyer's remorse. The Third Circuit concluded that a plaintiff lacked standing to sue L'Oréal for its failure to disclose that there were trace amounts of lead found in its lipstick in part because the plaintiff's "subjective allegation that the trace amounts of lead in the lipsticks are unacceptable to her" did not constitute injury-in-fact. *L'Oréal USA, Inc.*, 374 F. App'x at 259.[13] Without evidence that a product was illegal to sell, harmful, or overpriced, a plaintiff does not suffer injury from purchasing a product and later wishing that he or she had not done so. *See Herrington v. Johnson & Johnson Consumer*

[13] See Section IV, *supra*, for the Court's discussion of the Plaintiffs' reliance on subjective damages.

Cos., Inc., No. C 09-1597 CW, 2010 WL 3448531, at *5 (N.D. Cal. Sept. 1, 2010) (holding that the plaintiffs had failed to plead an injury in fact in part because the Consumer Product Safety Commission was merely monitoring the product at issue, not recalling it); *Doss v. Gen. Mills, Inc.*, No. 18-61924, 2019 WL 7946028, at *2 (S.D. Fla. June 14, 2019) (finding that a plaintiff lacked standing where she did not allege resulting, negative health effects from eating Cheerios), *aff'd*, 816 F. App'x 312 (11th Cir. 2020). A plaintiff "must allege facts that would permit a factfinder to value the purported injury at something more than zero dollars without resorting to mere conjecture." *Talc*, 903 F.3d at 285.

In this MDL, the Plaintiffs attempted, but were unable, to put forward reliable evidence to prove that ranitidine was unsafe, which now changes the Court's standing analysis. During the motion to dismiss stage, the standing theory on which the Plaintiffs relied for their economic loss class action claims had some similarities to *Debernardis* and *Aqua Dots* because the Court found that Plaintiffs in this MDL plausibly alleged that ranitidine was unsafe and should not have been sold, just like the supplements in *Debernardis* and the toys in *Aqua Dots*. After the Court's *Daubert* ruling, though, the Plaintiffs can no longer claim that ranitidine is unsafe or should not have been sold because of its cancer-causing propensity. As a result, the standing analysis for the economic loss class action claims is more similar to the analyses in *L'Oréal* and *In re Johnson & Johnson Talcum Powder Products Marketing, Sales Practices, and Liability Litigation*. 903 F.3d 278 (3d Cir. 2018). In *Talc*, the Third Circuit determined that a purchaser of baby powder did not have standing to pursue a refund for the product because she did not allege that it was unsafe; because the product was safe and effective, the plaintiff did not suffer an injury when she purchased it. *See id.* at 288-90.

Moreover, given the Court's *Daubert* ruling, the allegations in the SAELC, the Plaintiffs' prior concessions on the record and in their briefing, what the Plaintiffs are left with is a buyer's remorse case. The Plaintiffs purchased ranitidine. They do not allege that ranitidine did not perform as advertised; they do not allege that it caused them harm; and they cannot claim that ranitidine is unsafe or had only partial value (instead of no value).[14] Instead, what the Plaintiffs complain of, in their adulteration theory, is the presence of trace amounts of NDMA unconnected to evidence of human harm. This is precisely the sort of buyer's remorse case that federal courts dismiss for lack of standing. Therefore, for all of the reasons set forth in the caselaw cited above, the Plaintiffs have no viable economic injury-in-fact because, without evidence of harm, the Plaintiffs can only prove that they regret purchasing a product that performed as advertised. Because the Plaintiffs have not put forth any viable theory of injury-in-fact, the Plaintiffs do not have standing to pursue their economic loss class action claims.

VII. Conclusion

In summary, the Plaintiffs concede that their medical monitoring class action claims are no longer viable. Even if the Plaintiffs did not concede the viability of these claims, the Court concludes from its own analysis that the medical monitoring class action claims are no longer viable for all of the reasons stated in this Order. For this reason, the Court **GRANTS** summary judgment pursuant to Rule 56(f) and the Court's prior orders to cause under Rule 56(f) for the

[14] Although the Court can intuitively understand how a reasonable juror could conclude, using an objective standard, that a performing product has a reduced value because it contains impurities, the Court does not understand how a reasonable juror could assign the product a value of zero. In this MDL, the Plaintiffs abandoned the position that ranitidine could be worth more than zero. While the Court does not reach this analysis, the Court simply notes that, if it continued in its analysis of each economic loss class action claim, the Court likely would have determined that no reasonable juror could conclude that a product that performs as advertised, lacks any reliable evidence of cancer-causing propensity, lacks any reliable evidence that medical monitoring is warranted, and which has been taken by the named class Plaintiffs for decades without adverse effects, has a value of zero. A reasonable juror would have had to conclude ranitidine has some value, though jurors could debate what that value is.

Defendants on the Plaintiffs' medical monitoring class action claims. Because of the Court's entry of summary judgment, the Defendants are entitled to the entry of final judgment on the medical monitoring class action claims. The Clerk of the Court **SHALL ENTER** the final judgment attached to this Order as **Exhibit C** in each of the medical monitoring class action cases attached as **Exhibit A**.

Additionally, for all of the reasons set forth in this Order, the Plaintiffs lack standing to pursue their economic loss class action claims. When a district court concludes that a plaintiff does not have standing to bring their claims, the court must dismiss the claims without prejudice, even if this jurisdictional issue is discovered at the summary judgment stage of the litigation. *See City of Mia. Gardens v. Wells Fargo & Co.*, 931 F.3d 1274, 1278, 1288 (11th Cir. 2019). Accordingly, the Court **DISMISSES** the Plaintiffs' economic loss class action claims for lack of subject matter jurisdiction. The Clerk of the Court **SHALL ENTER** a copy of this Order in each case listed on **Exhibit B** and **CLOSE THOSE CASES** as **DISMISSED**.

The Plaintiffs' Motion to Stay [DE 6148] is **DENIED AS MOOT**.

DONE and ORDERED in Chambers at West Palm Beach, Florida, this 25th day of July, 2023.

Robin L. Rosenberg

ROBIN L. ROSENBERG
UNITED STATES DISTRICT JUDGE

Copies furnished to counsel of record